

REMARKS

Reconsideration of this application is respectfully requested in view of foregoing amendments and the following remarks.

Claims 3, 4, 8, 10, and 12-19 were pending in this application. In this amendment, claims 3, 4, and 12 have been amended. Accordingly, upon entry of this Amendment, claims 3, 4, 8, 10, and 12-19 will remain pending in this application.

In the Office Action mailed June 11, 2008, claims 3-4, 8, 10, and 12-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0039387 to Rutynowski et al. ("Rutynowski") in view of U.S. Patent No. 7,087,068 to Marshall et al. ("Marshall"). To the extent that this rejection might still be applied to the currently pending claims, Applicants respectfully traverse the rejections.

In particular, in addition to the reasons set forth in response to the Office Actions of September 11, 2006, March 9, 2007, and December 26, 2007, the cited art fails to render the pending claims obvious for the additional reasons detailed below.

The combination of Rutynowski and Marshall fails to teach or suggest the complete combination of elements recited in the pending claims, as currently amended, including independent claims 3, 4, and 12. In particular, the puncture force adjusting mechanism disclosed in Marshall is fundamentally different in structure and function from that of the present invention. In the Office Action, the Examiner acknowledged that Rutynowski fails to disclose a puncturing force adjusting member comprising an inwardly directed pair of oblique half-ring, stair-shaped, or gradient-shaped members. The Examiner relied upon the teachings of Marshall

to cure the deficiencies of Rutynowski. However, as explained below, the puncturing device of Marshall fails in several regards to teach or suggest the features of the present invention recited in the pending claims and missing from the disclosure of Rutynowski.

To underscore the differences in the puncture force adjusting member recited in the pending claims and the puncture device disclosed in Marshall, the detailed operation of the Marshall device is compared below to that of embodiments of the present invention.

The puncturing force adjustment member 39 (see Figure 7) of Marshall differs in its principle of operation significantly from the puncture force adjustment device of the present invention. As detailed below, Marshall discloses a puncture device in which the puncture force is *set and imparted* into a drive spring *before* actuation, while the present invention involves *setting* the puncture force before actuation is applied to the drive spring but *without imparting* the puncture force into the drive spring before actuation.

The puncturing force adjustment member 39 is engaged by its projections 42 in skew circumferential slots 43 of the barrel 11. Thus, by turning the puncturing force adjustment member 39, the puncturing force adjustment member 39 is caused to move axially along the barrel 11. The puncturing force adjustment member 39 supports one of the ends of the drive spring 38, whose second end abuts against a piston 29, which piston, in a first position of the device, is always in the same configuration relative to the barrel 11. In the first stable position of the device (before an actuation of the puncturing device), the drive spring 38 is held within a first distance corresponding to the distance between the face of the puncturing force adjustment member 39 and the proximal end of the piston 29, that is between the surfaces against which the

drive spring 38 abuts. Thus, a change of the position of the puncturing force adjustment member 39 causes a change of a distance between the puncturing force adjustment member 39 and the piston 29, and thereby a change of the length of the drive spring 38.

In the current Office Action, the Examiner refers to sleeve 44 as a push element, wherein a drive spring 38 is held within a first distance between a face of the push element and a piston 29. However, Applicants respectfully submit that the spring element 38 of Marshall is positioned between piston 29 on the one hand and puncturing force adjustment member 39 on the other hand, not sleeve 44.

The device of Marshall is also defined by a second distance, which is the distance along which the puncturing force adjustment member 39 can be moved towards the piston 29 until the cylindrical extension 37 of the piston 29 contacts adjustment member 39.

At the moment when button 34 is pushed to actuate the device of Marshall, the drive spring 38 pushes the piston 29 with a force that results from the compression of the spring 38 between the surfaces against which the drive spring 38 abuts, that is, the force resulting from spring 38 being disposed within a distance between the face of the puncturing force adjustment member 39 and the proximal end of the piston 29. This "third distance" is thus equal to the first distance of the device of Marshall discussed above.

When the desired puncturing force is adjusted by means of the puncturing force adjustment member 39, that is, when the first distance is adjusted, until the moment of the actuation of the puncturing device (pushing the trigger button 34), the puncturing force adjustment member 39 and the piston 29 remain stationary relative each to other. Thus, the

puncturing force adjustment member 39 adjusts the puncturing force by adjusting the first distance, which changes the initial biasing tension of the drive spring 38. The first distance remains constant thereafter until the moment of releasing the trigger button 34. Thus, the puncture force applied by the drive spring 38 to the piston 29 depends on the setting of the distance between the face of the puncturing force adjustment member 39 and the proximal end of the piston 29. For relatively low puncturing force, this first distance is greater and the tension force of the drive spring 38 is low, while for high puncturing force, the first distance is smaller and the tension force of the drive spring 38 is high.

In contrast to the puncturing device of Marshall, in embodiments of the present invention, the puncturing device comprises rotatable puncturing force adjusting members (*see, e.g.,* elements 39, 40 in Figures 4 and 5 or elements 42, 43 in Figures 6 and 7) that *do not move axially* while changing the setting of the puncturing force. This means that adjusting the puncturing force adjustment member has no effect on the initial biasing tension of the drive spring 10, which is constant and small. Thus, the puncturing force *to be applied* by drive spring 10 during actuation of the device *can be adjusted without changing the actual tension* of the drive spring *before* actuation.

In particular, in puncturing devices arranged in accordance with the present invention, adjusting the initial biasing tension of drive spring 10 has no effect on the distance between the faces of the push button 2 and the piston 5, *i.e.,* between the faces between which the drive spring 10 is placed (the first distance), which does not change. For clarity, in the present amendment, this first distance is recited in the amended independent claims to emphasize that

before actuation the drive spring has a length equal to the first distance between the push button face and piston, for example, as recited in amended claim 3 as follows: "when the device is in a first stable position before the push element is pushed, the face of the push element and the piston are separated by a first distance and the drive spring has a length equal to the first distance."

Puncturing devices arranged according to the present invention are also characterized by a second distance that is defined by the distance between the face of the adjusting members (39, 40 or 42, 43) and the upper end of the push rod 6. The second distance determines the stroke with which the push button 2 moves when putting the drive spring 10 under tension at the moment of the device actuation. When the push element 2 contacts the piston 5, further pressing of element 2 results in breaking of wings 12 of piston 5.

A third characteristic distance of the puncture device of the present invention is the distance into which the drive spring 10 is compressed at the moment of braking of wings 12, which distance equals the difference between the first and the second distances. As noted above, unlike the device of Marshall, in the puncturing device of the present invention, *adjusting the puncturing force does not change the first distance*. This feature is recited in the present independent claims as a puncturing force adjusting member, wherein the puncturing force adjusting member changes the second distance without changing the first distance.

However, in accordance with the puncturing device of the present invention, adjusting the puncturing force *does change* the second distance. This change in the second distance does thereby cause a change in the third distance (since the latter distance is the difference between

the first two distances), which is realized at the moment of device actuation, and which thereby adjusts the applied puncturing force.

In the Office Action, the Examiner has sketched a series of distances that are superimposed on Figure 7 of Marshall. In particular, a distance d1 is depicted as extending approximately from the top of piston 29 to a region near webs 54 (see Figure 9). However, it is not clear how this distance is judged to read on the feature previously recited in the independent claims, wherein the drive spring is held within a first distance within a first distance between the adjustable push element and the piston. Even if sleeve 44 were read to be a "push element," there is no indication of how the distance between web 54 and piston 29 corresponds to a distance within which a drive spring is held between piston 29 and sleeve 44. Moreover, as currently amended, the claims recite that the drive spring comprises the distance between a face of the push element and piston. There is clearly no drive spring in Figure 7 of Marshall that comprises the distance d1.

A distinct advantage afforded by the present puncturing device of the present invention, in comparison, for example, to that disclosed in Marshall, is that the initial biasing tension of the drive spring 10 is always the same before activation. Because the adjustable puncture force is not induced in the drive spring until activation, adjustment of the force adjusting element 38 before activation to any desired puncture force *has no effect on the actual force* in the drive spring before activation. Thus, the initial force in the drive spring 10 can be set to very small values, such that, during the life span of the puncturing device (that is, before this disposable puncturing device is used by the patient), the force acting on the piston 5 and on the breakable

wings 12 is small. This advantageously prolongs the life span and operational reliability of the puncturing device, and the drive spring in particular.

In summary, the principle of operation of the device of Marshall is completely different from that of the puncturing device recited in the present claims. Nowhere does Marshall teach or suggest a puncturing device having a puncturing force adjusting member defined by the first and second distances discussed above, wherein the puncturing force adjusting member changes a second distance so as to adjust a third distance in which the drive spring is compressed between the face of the push element and the piston at the operational position at which the puncturing force adjusting member presses the piston, *wherein the puncturing force adjusting member changes the second distance without changing the first distance*. In other words, nowhere does Marshall disclose that the puncture force is adjusted without adjusting the drive spring 38.

Moreover, there would be no motivation to combine the device of Rutynowski with the puncture force adjusting device of Marshall because the resulting arrangement would defeat the intended use of the device of Rutynowski. One of ordinary skill in the art, when apprised of the adjusting device of Marshall, would readily appreciate for the reasons discussed above that relatively large forces (that is, the desired puncturing forces) are induced in the initial stable state of the puncture force adjusting member of Marshall and that those large forces persist throughout the lifetime of the device until its one-time use. Those large puncturing forces would therefore act on the piston 5 of Rutynowski during the lifetime of the device before use and would likely result in partial deflection or breaking of the breakaway wings 12, thereby leading to unintentional self-activation of the puncturing device or its incorrect operation after intended

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activation. Accordingly, such a configuration would be recognized as dangerous for the patient, which would preclude its acceptance for the intended use.

In view of the foregoing, Applicants respectfully submit that all of the independent claims 3, 4, and 12, as well as their dependent claims 8, 10, and 13-19, are patentable over Rutynowski, in view of Marshall.

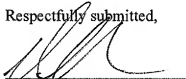
In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative at the number listed below.

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